

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P26592PC00/JV	FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/NL2004/000565	International filing date (day/month/year) 11.08.2004	Priority date (day/month/year) 17.09.2003
International Patent Classification (IPC) or national classification and IPC A61M27/00, A61M1/00		
Applicant BROOCKEVILLE CORPORATION N.V. ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 8 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
 - a. ☒ sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:
 - ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
 - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
 - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand 14.10.2005	Date of completion of this report 22.11.2005
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kousouretas, I Telephone No. +31 70 340-2449 

**INTERNATIONAL PRELIMINARY REPORT
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Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-15 as originally filed

Claims, Numbers

1-19, 21-27 as originally filed
20 received on 14.10.2005 with letter of 14.10.2005

Drawings, Sheets

1/4-4/4 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-17

because:

☒ the said international application, or the said claims Nos. 1-17 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	19
	No: Claims	18,20-27
Inventive step (IS)	Yes: Claims	19
	No: Claims	18,20-27
Industrial applicability (IA)	Yes: Claims	18-27
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item III

The examination has been performed on claims 18-27 only. The applicant has explicitly requested that only the above mentioned claims should be examined.

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

- 1 Reference is made to the following documents:

D1: FR-A-2 633 825 (AGA AB OY) 12 January 1990 (1990-01-12)
D2: DE 91 01 066 U1 (B. BRAUN MELSUNGEN AG, 3508 MELSUNGEN, DE) 18
April 1991 (1991-04-18)
D3: US-A-4 681 571 (NEHRING ET AL) 21 July 1987 (1987-07-21)
D4: US-A-4 551 141 (MCNEIL ET AL) 5 November 1985 (1985-11-05)

- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 18 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (see page 4, line 6- page 5, line 3 and figures, the references in parentheses applying to this document):

Collection container (suitable) for collecting exudate originating from a wound, comprising a flexible receiving container (2), which is in communication with a feed for conveying exudate from the wound to the receiving container, and a cover (6), comprising a closure rim, such that the cover can be positioned on an opening of a vacuum chamber (5) in a unique way.

The expression 'unique way' has been interpreted as 'unusual way' (see also point 6.4 below). It is also logical to assume that since the bottom of the container has an oval form, the upper part should also be oval. Positioning of a cover with a closure

rim which is oval takes place in an unusual way.

- 3 Dependent claims 20-27 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step. See for example:

D2 (search report) for claims 20,21

D3 (search report) for claims 22,23

D4 (search report) for claims 24,26,27

Finally, claim 25 is a design option obvious to the skilled person having no surprising or unexpected effect.

- 4.1 The combination of the features of dependent claim 19 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:
- 4.2 The subject-matter of claim 19 differs from the disclosure in D1 in that the closure rim is in the shape of an ellipse composed of two ellipse parts of different eccentricity which adjoin one another.

Therefore the subject-matter of claim 19 is new and meets the requirements of Art 33(2) PCT

- 4.3 The features cited at point 4.2 serve to position the cover onto the opening of the vacuum chamber in one way only. This serves to accurate positioning of the collection container into the vacuum chamber and guarantees a reproducible reading of the volume of the exudate collected in the container. None of the available prior art documents suggests the combination of said features with the remaining features of claim 19.

Therefore, claim 19 involves an inventive step and meets the requirements of Art 33(3) PCT.

- 4.4 The device disclosed in claim 19 is industrially manufacturable and therefore the claim meets the requirements of Art 33(4) PCT
- 4.5 Claims 20-27 will also meet the requirements of Art 33(2), (3) and (4) PCT if they refer to claim 19.

Re Item VII

- 5 The independent claim is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Re Item VIII

- 6.1 Claim 18 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined for the following reasons:
- 6.2 The reference to preceding claims 1-5 and 6-17 should be replaced by reference to the technical features of the wound drainage device and assembly disclosed in the above mentioned two sets of claims.
- 6.3 Claim 18 specifies the relationship of the closure rim to the opening of a vacuum chamber. However, the vacuum chamber as it stands is not part of the claimed invention (see Guidelines 5.37 PCT)

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- 6.4 The term 'unique way' can be interpreted in many ways. It can mean 'single way' or the 'only way', but it can also mean 'unusual way'.